

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)


Applicant's or agent's file reference 33034WOP00 RJD:rlc	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No.  PCT/AU03/00034	International Filing Date (day/month/year) 15 January 2003	Priority Date (day/month/year)  16 January 2002
International Patent Classification (IPC) or national classification and IPC  Int. Cl. <sup>7</sup> A43B 7/24, A61F 5/14		
Applicant  FOOT STEPS ORTHOTICS PTY LIMITED et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
- ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 7 August 2003	Date of completion of the report 19 September 2003
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  <b>JOHN HO</b> Telephone No. (02) 6283 2329

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☐ the international application as originally filed.
- ☒ the description, pages 1-7, as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☒ the claims, pages , as originally filed,  
pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages 8-9, received on 11 September 2003 with the letter of 11 September 2003
- ☒ the drawings, pages 1/7 - 7/7, as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims 1-16	YES
	Claims -	NO
Inventive step (IS)	Claims 1-16	YES
	Claims -	NO
Industrial applicability (IA)	Claims 1-16	YES
	Claims -	NO

**2. Citations and explanations (Rule 70.7)**

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 - US 5733647 A  
D2 - GB 2011243 A

The present claims are directed to an orthotic insert and a method of making such an insert having a first and second portion wherein the first and second portions are formed from heat mouldable ethyl vinyl acetate. The second portion is formed from a material of higher resistance to deformation than the first portion and wherein the second portion is adapted to provide support in the heel region of a person's foot.

These features are not disclosed in any of the citations. D1 discloses a removable insole having a thermoplastic layer formed from EVA. A heel cup, formed from *foam* EVA, is attached to the heel portion of the insole. This citation fails to disclose the use of a material having a greater resistance to deformation on the heel area. D2 discloses an insole having zones of different densities/elasticity. There is no disclosure of the use of heat mouldable ethyl vinyl acetate in D2.

Therefore the subject matter of these claims is new and meets the requirements of Article 33(2) PCT with regard to the requirement for novelty.

The claimed invention is not obvious in the light of any of the cited documents nor disclosed in any obvious combination, nor would the claimed invention be obvious to a person skilled in the art in the light of common general knowledge by itself or in combination with any of these documents.

**THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-**

1. An orthotic insert having a first and second portion, said second portion being formed of a material of higher resistance to deformation than said first portion, wherein  
5 said insert is heat mouldable to conform to a patient's foot.
2. The orthotic insert as claimed in claim 1, wherein the first and second portions of the orthotic insert are formed from resilient material, with the second portion being formed from a resilient material of higher resistance to deformation than said first portion.
- 10 3. The orthotic insert as claimed in claim 1 or 2, wherein the second portion is formed from a material of higher density than the material from which the first portion is made.
4. The orthotic insert as claimed in any one of claims 1 to 3, wherein said first and second portions of the orthotic insert are formed from ethyl vinyl acetate.
- 15 5. The orthotic insert as claimed in any one of claims 1 to 4, wherein said first and second portions of the orthotic insert are joined by bonding.
6. The orthotic insert as claimed in any one of claims 1 to 5, wherein the second portion is adapted to provide support for the heel region of a person's foot.
7. The orthotic insert as claimed in any one of claims 1 to 6, wherein the second  
20 portion is adapted to provide support for the heel and arch regions of a person's foot.
8. The orthotic insert as claimed in any one of claims 1 to 7, wherein the second portion has a substantially U- or J-shaped configuration which extends partially around the periphery of the insert corresponding to the heel and arch regions of a person's foot.
9. A method of producing an orthotic insert comprising forming a first portion of  
25 the insert from a heat mouldable material, forming a second portion of the insert from a

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ART 34

heat mouldable material of higher resistance to deformation than said first portion of the insert, and joining said first and second portions together to form the insert.

10. The method of producing an orthotic insert as claimed in claim 9, wherein the first portion of the insert is formed by moulding.
- 5 11. The method of producing an orthotic insert as claimed in claim 10, wherein the first portion of the insert is formed by heat moulding.
12. The method of producing an orthotic insert as claimed in any one of claims 9 to 11, wherein the second portion of the insert is formed by moulding.
13. 13. The method of producing an orthotic insert as claimed in claim 12, wherein the  
10 second portion of the insert is formed by heat moulding.
14. The method of producing an orthotic insert as claimed in any one of claims 9 to 13, wherein the said first and second portions are joined together by means of bonding.